K123457

MAR 2 2 2013

510(k) Summary

NAME OF SPONSOR:	Ortho Development Corporation 12187 South Business Park Drive Draper, Utah 84020
510(k) CONTACT:	Tom Haueter Regulatory Affairs Manager Telephone: (801) 553-9991 Facsimile: (801) 553-9993 Email: thaueter@orthodevelopment.com
DATE PREPARED:	October 29, 2012
PROPRIETARY NAME:	Balanced Knee System High Flex PS
COMMON NAME:	Total Knee Replacement Prosthesis
CLASSIFICATION:	21 CFR 888.3560, Knee joint, patellofemorotibial, polymer/metal/polymer semi-constrained cemented prosthesis, Class II device
DEVICE PRODUCT CODE:	JWH
PREDICATE DEVICES:	Balanced Knee System (K994370), *Ortho Development Corp.* LPS-Flex Fixed Bearing Femoral and Articular Surface Components (K991581), *Zimmer*

Device Description

The Balanced Knee System High Flex PS (High Flex PS) is designed to accommodate increased range of motion up to 150° of flexion. The High Flex PS includes a highly polished Co-Cr-Mo PS femoral component and a compression molded UHMWPE PS tibial insert component. The High Flex PS femoral and insert components may be used in conjunction with the Balanced Knee System (BKS) standard and modular tibial trays, tibial augments, stems, and patellae to complete the semi-constrained modular knee prosthesis.

Intended Use

The Balanced Knee System High Flex PS is intended for use in cemented total knee arthroplasty procedures with the following indications:

1. Loss of knee joint configuration and joint function.
2. Osteoarthritis of the knee joint.
3. Rheumatoid arthritis of the knee joint.
4. Post-traumatic arthritis of the knee joint.
5. Valgus, varus, or flexion deformities of the knee joint.
6. Revision procedures where other treatments or devices have failed.

Performance Data

Property	Result
Range of Motion	Up to 150° flexion; Similar to predicate device, LPS-Flex
Femoral Fatigue	Improved Fatigue Strength over predicate device, BKS; Sufficient strength to survive in-vivo loading
Femorotibial Constraint	Similar to predicate device, BKS
Femorotibial Contact Area	Similar to predicate device, BKS
Patellofemoral Constraint	Similar to predicate device, BKS
Patellofemoral Contact Area	Similar to predicate device, BKS
PS Spine Fatigue	Sufficient strength to survive in-vivo loading

Basis for Substantial Equivalence

Ortho Development believes that the Balanced Knee System High Flex PS is substantially equivalent to the previously cleared predicate devices based on similarities in intended use, design, materials, manufacturing methods, packaging, and mechanical performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 22, 2013

Ortho Development Corporation
% Mr. Tom Haueter
Regulatory Affairs Manager
12187 South Business Park Drive
Draper, Utah 84020

Re: K123457
Trade/Device Name: Balanced Knee® System High Flex PS
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: February 8, 2013
Received: February 21, 2013

Dear Mr. Haueter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use Form
Ortho Development
Balanced Knee® System High Flex PS 510(k)

510(k) Number (if known): K123457

Device Name: Balanced Knee® System High Flex PS

Indications for Use:

The Balanced Knee® System High Flex PS is intended for use in cemented total knee arthroplasty procedures.

Total knee arthroplasty is indicated for the following conditions:

1. Loss of knee joint configuration and joint function.
2. Osteoarthritis of the knee joint.
3. Rheumatoid arthritis of the knee joint.
4. Post-traumatic arthritis of the knee joint.
5. Valgus, varus, or flexion deformities of the knee joint.
6. Revision procedures where other treatments or devices have failed.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopaedic Devices